K051366/S2
p1 of 2

SEP 14 2005

510(k) Summary

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 C.F.R. §807.92.

1. The submitter of this premarket notification is:

Markus Stacha
Philips Medizin Systeme Boeblingen GmbH
Hewlett-Packard-Str. 2
D-71034 Boeblingen, Germany
Tel: ++49 7031 463-2840 Fax: ++49 7031 463-2442
Email: markus.stacha@philips.com

This summary was prepared on August 02, 2005.

2. The name of the device is the picoNIBP OEM module. Classification name is as follows:

Device Panel	Classification	ProCode	Description
Cardiovascular Diagnostic Devices	§870.1130, II	DXN	Non-Invasive Blood-Pressure Measurement System

3. The new device picoNIBP OEM module is in respect of non-invasive blood pressure (NIBP) substantially equivalent to previously cleared Philips Multi-Parameter Module M3001A marketed pursuant to K020531 (March 20, 2002) and Philips Measurement Server M3000A K001333 (May, 17, 2000). The new device is in respect of pulse rate substantially equivalent to the Philips Series 50XM (M1350B) Fetal/Maternal Monitor K954351 (March 08, 1996).

4. The new device picoNIBP OEM module reuses the NIBP portion and the NIBP algorithm of the legally marketed Philips Multi-Parameter Module M3001A. The calculation of the pulse rate in the new device picoNIBP OEM module is carried out with exactly the same pulse rate algorithm as in the predicate device Philips Series 50XM (M1350B) Fetal/Maternal Monitor. The picoNIBP OEM module is a complete non-invasive arterial blood pressure measurement component intended for use in patient monitors. The picoNIBP OEM module incorporates all hardware control and signal processing and also the algorithms to derive systolic, diastolic, and mean blood pressure as well as the pulse rate. The derived data is provided to the patient monitor that incorporates the picoNIBP OEM module.

5. The picoNIBP OEM module is intended for integration in patient monitors for measurement of blood pressure and for calculation of pulse rate of adults, pediatrics, and neonates in health care facilities.

6. The new device picoNIBP OEM module has the same intended use and technological characteristics as the NIBP portion of the legally marketed predicate devices.

7. Verification and validation testing activities were conducted to establish the performance, functionality, and reliability characteristics of the new device picoNIBP OEM module.
Testing involved environmental, functional level tests, accuracy determination and safety and performance testing from the risk analysis. Pass/Fail criteria were based on standards and on the specifications cleared for the predicate device.
Test results demonstrated that the picoNIBP OEM module meets all reliability requirements and performance claims and showed substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 14 2005

Philips Medizin Systeme Böblingen GmbH
c/o Mr. Markus Stacha
Senior Regulatory Affairs Engineer
Cardiac and Monitoring Systems
Hewlett-Packard Str. 2
D-71034 Böblingen
Germany

Re: K051366
Trade Name: picoNIBP OEM Module
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 2, 2005
Received: August 5, 2005

Dear Mr. Stacha:

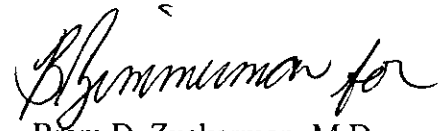
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295.. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K051366/S2

Indications for Use

510(k) Number (if known):_____

Device Name: picoNIBP OEM module.

Indications for Use: Indicated for use by health care professionals whenever there is a need for measuring the non-invasive blood pressure and pulse rate of patients.
It is intended for use in patient monitors for measurement of blood pressure and for calculation of pulse rate of adults, pediatrics, and neonates in health care facilities.

Prescription Use yes (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use No (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K051366